REMARKS

STATUS OF THE CLAIMS.

Claims 7, 8, 88, 90, 92, 93, 97, 98, 100, and 101-103 are pending with entry of this amendment, claims 6, 87, 89, 91, 94-96, and 99 being cancelled herein, and claims 102 and 103 being added. Claims 7, 8, 92, 93, 97, 98, 100, and 101 are amended herein. These amendments introduce no new matter and support is replete throughout the specification. Support for claims 102 and 103 is found in Applicant's specification at least at page 26, lines 27-31. These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record.

35 U.S.C. §112, FIRST PARAGRAPH.

Claims 6-8, 89, 91, 96, and 99 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Office Action, page 2. Applicant respectfully traverses the rejection.

Of the rejected claims, only claims 7 and 8 remain pending. These claims were rejected for reciting an interleukin-8 (IL-8) fragment "no greater than about 15 amino acids in length," which the Examiner contends is insufficiently described in the specification. Office Action, page 3. Claim 7 has been amended to recite "no greater than about 8 amino acids in length." This element previously appeared in claim 99, which the Examiner also believes finds insufficient support in the specification. The rationale for the rejection is that the specification indicates that the IL-8 fragments can be longer than 8 or 15 amino acids in length. The Examiner asserts that, therefore, "the upper limit contemplated was 'greater than about 8' and 'than about 15'." *Id.*

"The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.'" *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000) (citations omitted). With respect to the length of the claimed IL-8 fragment, Applicant's specification states:

> The chemokine [*e.g.*, IL-8] fragment must be large enough to include a functional differentiation domain. Chemokine fragments useful in the invention can, for example, range from about 5 to about 50 amino

> acids in length, although other lengths are possible. Preferred fragments range from about 8 to about 25 amino acids, and more preferably from about 8 to about 15 amino acids.

Applicant's specification, page 26, lines 27-31. From the teaching that exemplary fragments can "range from about 5 to about 50 amino acids in length," one skilled in the art understands that exemplary fragments can be 5, 6, 7, 8, and so on, up to about 50, amino acids in length, although one also understands that "other lengths are possible," so long as the fragment includes a functional differentiation domain. The specification discloses a specific example of an IL-8 fragment of 6 amino acids in length (SAKELR; SEQ ID NO.:8). The Examiner is correct that longer fragments were ***also*** contemplated. But the specification's disclosure that the fragments ***could*** be longer does not negate the clear teaching that the fragments could be, for example, about 5,6, 7, or 8 amino acids in length. Accordingly, Applicant submits that the specification clearly conveys to those of ordinary skill in the art that Applicant invented the polypeptide of claim 7, which is "no greater than about 8 amino acids in length."

From the teaching that exemplary fragments can "range from about 5 to about 50 amino acids in length," one skilled in the art understands that exemplary fragments can be 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15 and so on, up to 50, amino acids in length, although one also understands that "other lengths are possible," so long as the fragment includes a functional differentiation domain. The specification discloses specific examples of IL-8 fragments of 6 (SAKELR; SEQ ID NO.:8) and 11 (AVLPRSAKELR; SEQ ID NO.:9) amino acids in length. Moreover, the specification explicitly recites an exemplary length range with "about 15 amino acids" as the upper limit. The fact that the specification contemplates ***other*** embodiments is simply irrelevant to the question of whether the embodiment now recited in claim 8, wherein the IL-8 fragment is "no greater than about 15 amino acids in length, is adequately supported in the specification. Given that the specification contains, *ipsis verbis* support for an upper length limit of about 15 amino acids, those of ordinary skill in the art could not help but recognize that the Applicant "invented what is claimed." Accordingly, the *Union Oil* test for compliance with the written description requirement is fully satisfied.

The present factual situation is analogous to that in *In re Johnson*, 558 F.2d 1008 (C.C.P.A. 1977). In that case, the court characterized the written description issue as "whether, after exclusion from the original claims of two species specifically disclosed in the 1963 application, the

1963 disclosure satisfies § 112, first paragraph, for the 'limited genus' now claimed." *Id.* at 1017-18. In that case, as in the present case, the appellant claimed a subset of what was originally disclosed in the specification at issue. The court analyzed this issue as follows:

> While the board found that "no antecedent basis exists in the parent case" for the "limited genus" in claim 1, we see more than ample basis for claims of such scope. The 1963 disclosure is clearly directed to polymers of the type claimed. Fifty specific choices are mentioned for the E precursor compound, a broad *class* is identified as embracing suitable *choices* for the E' precursor compound, and twenty-six "examples" are disclosed which detail fifteen species of polyarylene polyethers. Only fourteen of those species and twenty-three of the "examples" are within the scope of the claims now on appeal. Two of the many choices for E and E' precursor compounds are deleted from the protection sought, because appellant is *claiming less* than the full scope of his disclosure. But, as we said in *In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976):*
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> > Inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable.
>
> ***It is for the inventor to decide what bounds of protection he will seek.*** *In re Saunders, 58 CCPA 1316, 1327, 444 F.2d 599, 607, 170 USPQ 213, 220 (1971).* ***To deny appellants the benefit of their grandparent application in this case would, as this court said in Saunders:***
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> > **** * * let form triumph over substance, substantially eliminating the right of an applicant to retreat to an otherwise patentable species merely because he erroneously thought he was first with the genus when he filed.***
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> * * *
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> ***The notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species there within***, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and ***has thus failed to satisfy the requirements of § 112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute.*** All that happened here is that appellants narrowed their claims to avoid having them read on a lost interference count.

> The board indicated that "it is manifestly immaterial" *why* appellants limited their claims. Though it is true that insufficiency under § 112 could not be cured by citing the causes for such insufficiency, it is not true that the factual context out of which the question under § 112 arises is immaterial. Quite the contrary. ***Here, as we hold*** on the facts of this case, the "written description" in ***the 1963 specification*** supported the claims in the absence of the limitation, and that specification, ***having described the whole, necessarily described the part remaining.*** The facts of the prosecution are properly presented and relied on, under these circumstances, to indicate that ***appellants are merely excising the invention of another, to which they are not entitled, and are not creating an "artificial subgenus" or claiming "new matter***."

Id. at 1018-19 (bold italics added). By the same token, Applicant has explicitly described a genus of about 5 to about 50 amino acids in length, with subgenuses of about 8 to about 25 and about 8 to about 15 and specific examples of 6 and 11. Applicants submit that the notion that this disclosure fails to satisfy § 112, first paragraph with respect to the recitations, in claims 7 and 8, of "not greater than about 8" or "not greater than about 15" (respectively) can only "result from a hypertechnical application of legalistic prose relating to that provision of the statute." *Id.* As the *Johnson* court has unambiguously condemned this mechanistic application of the statute, Applicants submit that the § 112, first paragraph rejection for failure to satisfy the written description requirement cannot properly be maintained. Withdrawal of this rejection is therefore respectfully requested.

Claims 6, 7, 87, 89, and 91-99 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Office Action, page 4. Applicant respectfully traverses this rejection.

Of the rejected claims, only claims 7, 92, 93, 97, and 98 remain pending, of which, only claim 7 is independent. Claim 7 previously recited an IL-8 fragment that, *inter alia*, was "at least 90% identical to an N-terminal sequence of IL-8." This claim was rejected on the ground that "Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the *specific positions* in the protein which are tolerant to change . . . while still maintaining the function of stimulating the differentiation of fibroblasts to myofibroblasts." Office Action, page 5. As claim 7 has been amended to recite that the IL-8 fragment is identical to "an N-terminal amino acid sequence of IL-8" (which the claim goes on to define), Applicant submits that the rejection of claim 7 is now moot.

None of the pending independent claims (Claims 7, 8, 88, or 90) recites an IL-8 amino acid sequence variant. Rejected claims 92, 93, 97, and 98 are all dependent claims and also do not recite IL-8 amino acid sequence variants. Accordingly, claims 7, 92, 93, 97, and 98 are all free of the § 112, first paragraph rejection for failure to comply with the enablement requirement. Withdrawal of the rejection is therefore respectfully requested.

35 U.S.C. §102.

Claims 6-8, 88, 90, 92, 95, 97, 98, 100, and 101 were rejected under 35 U.S.C. § 102(b) as anticipated by Stern *et al.*, U.S.P.N. 5,641,867. Office Action, page 6. This rejection is respectfully traversed.

Of the rejected claims, claims 7, 8, 88, 90, 92, 97, 98, 100, and 101 remain pending. Claims 7, 8, 88, and 90 are independent.

Claim 7 recites a "polypeptide comprising a single interleukin-8 (IL-8) fragment, wherein said IL-8 fragment stimulates the differentiation of fibroblasts to myofibroblasts, and wherein said fragment comprises an ELR motif and an amino acid sequence that is identical to an N-terminal amino acid sequence of IL-8, and is no greater than about 8 amino acids in length, wherein the N-terminal amino acid sequence comprises a subsequence of residues 1-36 of SEQ ID NO.: 5 or residues 1-38 of SEQ ID NO.: 4."

According to the Examiner:

> Stern teaches a peptide derived from the ELR-region of IL-8 (SEQ ID NO:17). The peptide of Stern comprises the ELR motif and is 12 amino acids long.

Office Action, page 7. This peptide is distinguished from the polypeptide of claim 7 in that claim 7 requires an IL-8 fragment of no greater than about 8 amino acids in length. Therefore, Stern does not anticipate claim 7. Applicant notes that the 8-amino acid length limit was previously recited in claim 99, which previously depended from claim 7 and is now canceled. As claim 99, quite properly, was not rejected over Stern, it is believed that the Examiner recognizes that this length limit effectively distinguishes the claimed invention from the disclosures of Stern.

Independent claim 8 recites:

> A polypeptide comprising a single interleukin-8 (IL-8) fragment, wherein the IL-8 fragment comprises an amino acid sequence selected from the group consisting of SEQ ID NO:8 and SEQ ID NO:9, and is

no greater than about 15 amino acids in length, wherein the polypeptide is a cyclic polypeptide.

Stern teaches nothing regarding cyclic polypeptides, much less anything about cyclic polypeptides comprising an IL-8 fragment. The requirement that the polypeptide be cyclic was previously recited in claim 87, which previously depended from claims 6, 7, or 8. This claim has now been canceled and the "cyclic polypeptide" requirement has been incorporated into claim 8. Applicant notes claim 87 was not rejected over Stern, indicating that the Examiner recognizes that Stern fails to teach a cyclic form of the polypeptide of claim 8.

Independent claim 88 recites: "A polypeptide comprising a single interleukin-8 (IL-8) fragment, wherein said IL-8 fragment consists of amino acid sequence SAKELR (SEQ ID NO.: 8)." It is well-settled that the transitional term "consists of" is "closed language," which is interpreted as excluding additional elements. *See, e.g., AFG Indus. v. Cardinal IG Co.*, 239 F.3d 1239, 1245 (Fed. Cir. 2001). Therefore, this claim recites a polypeptide that has only one IL-8 fragment, and that fragment can only encompass the amino acid sequence SAKELR--no more and no less. Put differently, the ***only*** IL-8 sequence that can appear in the claimed polypeptide is SAKELR. As the Examiner notes, Stern's SEQ ID NO:17 is a 12 amino acid-long IL-8 sequence. Clearly, this sequence contains a different (longer) IL-8 fragment than that recited in claim 88. Thus, Stern does not anticipate claim 88.

A similar rationale applies to independent claim 90. This claim recites: "A polypeptide comprising a single interleukin-8 (IL-8) fragment, wherein said IL-8 fragment consists of amino acid sequence AVLPRSAKELR (SEQ ID NO.: 9)." Thus, the ***only*** IL-8 sequence that can appear in the claimed polypeptide is AVLPRSAKELR. As stated by the Examiner, "the peptide of Stern (SEQ ID NO:17) is one amino acid longer than SEQ ID NO: 9 . . . ." Office Action, page 7. Therefore, Stern's SEQ ID NO:17 contains a different (longer) IL-8 fragment than that recited in claim 90. Thus, Stern does not anticipate claim 90.

The remaining rejected claims, claims 92, 97, 98, 100, and 101 depend from one or more of the above-discussed independent claims. These claims are therefore free of the rejection over Stern for at least the reasons discussed above for one or more of claims 7, 8, 88, and 90. Withdrawal of the § 102 rejection is therefore respectfully requested.

In view of the foregoing, Applicant believes that all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early

date is respectfully requested. Should the Examiner seek to maintain the rejections, Applicant requests a telephone interview with the Examiner and the Examiner's supervisor.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3509.

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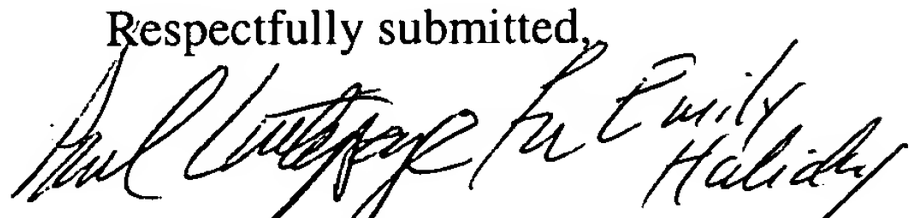
Respectfully submitted,



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